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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,336	01/31/2001	Jose Pozuelo	POZ 2 0004-3	4263

7590

09/03/2002

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EXAMINER
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CELSA, BENNETT M

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 09/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

File  
way

# Office Action Summary

Application No.

09/773,336

Applicant(s)

Pozuelo

Examiner

Bennett Celsa

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-19 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

Claims 1-19 are currently pending.

#### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7 and 17-19, drawn to a composition comprising alpha-methyl-para-tyrosine (ampt) and haldol, classified in class 546, subclass 218.
  - II. Claim 8, drawn to a composition comprising ampt and naltrexone, classified in class 546, subclass 45.
  - III. Claims 9-15 (in part), drawn to a method of treating narcotic (marijuana/cocaine/heroin/amphetamine) addiction by administering ampt and haldol, classified in class 514, subclass 812.
  - IV.. Claims 9-14 (in part), drawn to a method of treating nicotine addiction by administering ampt and haldol, classified in class 514, subclass 813.
  - V.. Claims 9-15 (in part), drawn to a method of treating alcoholism by administering ampt and haldol, classified in class 514, subclass 811.
  - VI. Claims 9-14 (in part), drawn to a method of treating schizophrenia or manic depressive psychosis, classified in class 514, subclass 327.
  - VII. Claim 16, drawn to a method of treating alcoholism by administering ampt and naltrexone, classified in class 514, subclass 282.

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The inventions are distinct, each from the other because:

2. Inventions I and II are directed to independent and/or patentably distinct compositions since the compositions required different compounds (e.g. haldol vs. naltrexone) of unrelated structure and biological/physicochemical properties; which have different modes of operation, different functions, or different effects .
3. Inventions III-VII are directed to independent and/or patentably distinct methods due to differences in method objectives encompassing disease states possessing different etiologies, symptoms and treatment modalities (e.g. narcotic v. nicotine v. alcohol addictions, schizophrenia); utilize different pharmaceutical compositions (e.g. ampt and haldol v. ampt and naltrexone); and which require different dosage formulations and treatment regimens.
4. Inventions I and (III or IV or V or VI ) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as the use of a nicotine patch to treat nicotine addiction or eskazine to treat schizophrenia (e.g. see also specification pages 1-2). Additionally, the product as claimed can be used in a materially different process of using that product such as in Groups III or IV or V or VI .

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5. Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product (e.g. to treat alcoholism) as claimed can be practiced with another materially different product such as Antabuse (e.g. active ingredient Disulfiram)

6. Because these inventions are distinct for the reasons given above and have:

- a. acquired a separate status in the art as shown by their different classification: and/or
- b. are drawn to divergent subject matter and/or
- c. the search required for the different groups is different and individually and separately burdensome (e.g. manual and computer; patent and literature databases); restriction for examination purposes as indicated is proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe McKane (art unit 1627), can be reached at (703)308-4537.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)  
August 28, 2002

BENNETT CELSA  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'Bennett Celsa', written over the printed name and title.